Claims

1. A process for obtaining HMG-CoA reductase inhibitors, characterised in that one of the steps in the process of the purification of crude HMG-CoA reductase inhibitors includes displacement chromatography which involves the use of a displacer for displacing the HMG-CoA reductase inhibitor.

2. A process according to claim 1, characterised in that the HMG-CoA reductase inhibitor is selected from the group consisting of mevastatin, pravastatin, lovastatin, simvastatin, fluvastatin and atorvastatin.

3. A process according to claim 1 or 2, characterised in that the HMG-CoA reductase inhibitor is in the lactone form or in the form of the acid or the salt thereof.

4. A process according any one of claims 1 to 3, characterised in that the displacement chromatography includes the following steps:

a) conditioning a chromatography column with a mobile phase,

b) feeding HMG-CoA reductase inhibitor dissolved in the mobile phase,

c) introducing the displacer for displacing the HMG-CoA reductase inhibitor from the column, and

d) obtaining the purified HMG-CoA reductase inhibitor.

5. A process according to claim 4, characterised in that the purified HMG-CoA reductase inhibitor is obtained by

d1) collecting the fractions, and

d2) analyzing the fractions with analytical HPLC and pooling the fractions depending on the quality of purity.

B

6. A process according to claim 4 or 5, characterised in that the displacement chromatography further ~~includes~~ consists of the subsequent step of:

e) regenerating the chromatography column by washing the column with alcohol/water mixture to elute the displacer.

7. A process according to claim 4, characterised in that the mobile phase is selected from the group of solvents consisting of water, acetonitrile/water solutions or aqueous solutions of lower alcohols, as well as bufferred dilute solutions of organic, halogenated organic or inorganic acids with alkaline metal cations, with ammonia or with amines.

8. A process according to claim 7, characterised in that the mobile phase is any one of water, an acetonitrile/water solution or an aqueous solution of lower alcohols.

9. A process according to claim 4, characterised in that the pH of the mobile phase used is between 4.5 and 10.5.

10. A process according to claim 9, characterised in that the pH of the mobile phase used is between 6.5 and 8.

11. A process according to claim 10, characterised in that the pH of the mobile phase used is 7.

12. A process according to claim 4, characterised in that the flow rate of the mobile phase through the chromatographic column is between 1.5 and 30 ml/(min cm^2).

13. A process according to claim 4, characterised in that the flow rate of the mobile phase/displacer mixture through the chromatographic column is between 3 and 15 ml/(min cm^2).

14. A process according to claim 6, characterised in that the stationary phase is regenerated with 20 to 100% aqueous solution of lower alcohols after completed chromatography.

15. A process according to claim 4, characterised in that the stationary phase is a reverse phase.

16. A process according to claim 15, characterised in that the stationary phase is a natural reverse phase such as silica gel with alkyl chains of different lengths.

17. A process according to claim 15, characterised in that the stationary phase is either C-18 or C-8.

18. A process according to claim 15, characterised in that the stationary phase is a synthetic cross-linked polymer matrix.

19. A process according to claim 18, characterised in that the cross-linked polymer matrix is a copolymer of styrene and divinylbenzene.

20. A process according to claim 4, characterised in that the particle size of the stationary phase is between 3 and 20 µm.

21. A process according to claim 20, characterised in that the particle size of the stationary phase is between 7 and 15 µm.

22. A process according to claim 4, characterised in that the displacer is selected from the group consisting of long chain alcohols, long chain carboxylic acids, long chain alkyl ammonium salts, aromatic dicarboxylic acid

esters, oxo- and dioxo-alcohols, polyalkylene polyglycol ethers and polyaryl or polyalkylene polyaryl ethers.

23. A process according to claim 4, characterised in that the concentration of the displacer in the mobile phase is between 1 and 35%.

24. A process according to claim 23, characterised in that the concentration of the displacer in the mobile phase is between 2 and 20%.

25. The use of a process according to any one of claims 1 to 24 for producing a HMG-CoA reductase inhibitor with a HPLC purity exceeding 99.7%.